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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/801,389	03/12/2004	Frank W.R. Chaplen	245-67734-01	3168

24197 7590 11/02/2006

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EXAMINER	
SIMS, JASON M	

ART UNIT	PAPER NUMBER
1631	

DATE MAILED: 11/02/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/801,389	CHAPLEN ET AL.	
	Examiner	Art Unit	
	Jason M. Sims	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 August 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-94 and 108-117* is/are pending in the application.

4a) Of the above claim(s) *3-6,11,28-77,79,84-107,112-114,116 and 117* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,7-27,78,80-83,108-110 and 115* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *4/14/05 and 12/5/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicant's election of group I, claims 1-94 and 108-117, and the following election of species; living cells, non-pigmented cells, cellular processes, metabolism, and mass spectrometry, in the reply filed on 8/22/2006 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 3-6, 28-77, 79, 84-107, 11, 112-114, and 116-117 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to nonelected species, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 8/22/2006.

Applicant has cancelled claims 95-107.

Claims 1-2, 7-27, 78, 80-83, 108-110, and 115 are the current claims hereby under examination.

Claim Objections

Claim 112 is an improper dependent claim and has been withdrawn from further consideration as noted above in the instant office action.

Claim Rejections - 35 USC § 112

Claims 1-2, 7-27, 78, 80-83, 108-110, and 115 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 contains the wording "representing a response of the system," which is vague and indefinite as to what exactly the word "representing" refers. It appears that the word "representing" refers to a computer representation of the response in order to perform a database comparison. Clearer claim wording is required.

Claims 8 and 9 contain the wording "software expert parameters" and "expert parameters," which is vague and indefinite as to what it means. It is not clear from the claim wording or the specification as to what the wording "software expert parameters" or "expert parameters" means. Clearer claim wording is required.

Claim 9 and 10 contain the wording "expert," which is vague and indefinite as to what it means. It is not clear from the claim wording or the specification as to what the wording "expert" means. Clearer claim wording is required.

Claims 11, 17-18, 23, and 26 contain the wording "simplex scenarios," which is vague and indefinite as to what it means. It is not clear from the claim wording or the specification as to what the wording "simplex scenario" means. Clearer claim wording is required.

Claims 13 and 15 contains the wording "software experts," which is vague and indefinite as to what it means. It is not clear from the claim wording or the specification as to what the wording "software experts" means. Clearer claim wording is required.

Claims 16, 24, and 27 contain the wording "complex scenario," which is vague and indefinite. It is unclear as to what exactly constitutes a complex scenario. The language of claim 16 states a complex scenario is synthesized from known scenarios. It appears that any number of known scenarios, ranging from one or more, used to

synthesize a complex scenario, read on the broad interpretation of the meaning of a complex scenario. Clearer claim wording is required.

Claim 18 contains the wording "where each simplex scenario is an elicitor," which is vague and indefinite as to what it means. In independent claim 1, a scenario appears to be what is produced as the result of exposing a system to a bioactive condition. In light of the instant specification, an elicitor appears to be in context of a bioactive condition and from common knowledge in the art, refers to some type of compound that may elicit some response that would, in the context of the instant claim language, produce a scenario. Therefore, the wording of claim 18, where what is produced, "the simplex scenario," being equal to what causes the result, "the elicitor," is confusing. Clearer claim wording is required.

Claims 24 and 27 contain the wording "determining the probability that the complex scenario is a complex scenario" and "determining the likelihood that the complex scenario is a complex scenario" is vague and indefinite. It is confusing to understand how determining what is already known is known would need a "determining probability" or a "determining likelihood" or could be anything other than a 100% chance. Clearer claim wording is required.

Claim 78 contains the wording "orthogonal biological system responses," which is vague and indefinite as to what it means. It is not clear from the claim wording or in light of the instant specification as to what the wording "orthogonal biological system responses" means. Clearer claim wording is required.

Claims 2, 7, 12, 14, 19-22, 25-26, 80-82, 108-110, and 115 are being rejected as being dependent from a rejected claim.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1 and 7-27, 78, and 80-83 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

Under the Interim Guidelines for Examination of Patent Applications for Patent Subject Matter Eligibility (published in the O.G. notice (1300 OG 142) on 11/22/2005) a method that does not result in a physical transformation of matter MAY be statutory where it recites a concrete, tangible and useful result; i.e. a practical application.

Claims 1, 7-27, 78, and 80-83 are drawn to a process. A statutory process must include a step of a physical transformation, or produce a useful, concrete, and tangible result (State Street Bank & Trust Co. v. Signature Financial Group Inc. CAFC 47 USPQ2d 1596 (1998), AT&T Corp. v. Excel Communications Inc. (CAFC 50 USPQ2d 1447 (1999)). In the instant claims, there is no step of physical transformation, thus the Examiner must determine if the instant claims include a useful, concrete, and tangible result.

As noted in State Street Bank & Trust Co. v. Signature Financial Group Inc. CAFC 47 USPQ2d 1596 (1998) below, the statutory category of the claimed subject

matter is not relevant to a determination of whether the claimed subject matter produces a useful, concrete, and tangible result:

The question of whether a claim encompasses statutory subject matter should not focus on *which* of the four categories of subject matter a claim is directed to 9 -- process, machine, manufacture, or composition of matter--but rather on the essential characteristics of the subject matter, in particular, its practical utility. Section 101 specifies that statutory subject matter must also satisfy the other "conditions and requirements" of Title 35, including novelty, nonobviousness, and adequacy of disclosure and notice. *See In re Warmerdam* , 33 F.3d 1354, 1359, 31 USPQ2d 1754, 1757-58 (Fed. Cir. 1994). For purpose of our analysis, as noted above, claim 1 is directed to a machine programmed with the Hub and Spoke software and admittedly produces a "useful, concrete, and tangible result." *Alappat*, 33 F.3d at 1544, 31 USPQ2d at 1557. This renders it statutory subject matter, even if the useful result is expressed in numbers, such as price, profit, percentage, cost, or loss.

In determining if the claimed subject matter produces a useful, concrete, and tangible result, the Examiner must determine each standard individually. For a claim to be "useful," the claim must produce a result that is specific, and substantial. For a claim to be "concrete," the process must have a result that is reproducible. For a claim to be "tangible," the process must produce a real world result. Furthermore, the claim must be limited only to statutory embodiments.

Claims 1, 7-27, 78, and 80-83 do not produce a tangible result. A tangible result requires that the claim must set forth a practical application to produce a real-world

result. This rejection could be overcome by amendment of the claims to recite that a result of the method is outputted to a display or a memory or another computer on a network, or outputting the result to a user, or by including a physical transformation.

Additionally, claims 1, 7-27, 78, and 80-83 contain the limitation with the wording "exposing a system to a bioactive condition," which is broadly interpreted as being able to be performed solely within a computer system that models a biological system. The claim language does not specifically read on a system that requires a physical transformation such as a system that is comprised of living cells as in claim 2. Therefore, claims 1, 7-27, 78, and 80-83 are able to read on nonstatutory subject matter and have been rejected as such.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 1-2, 7, 12-16, 80-82, and 108-110 are rejected under 35 U.S.C. 102(e) as being anticipated by Bevilacqua et al. (US P/N 6,692,916).

The claims are directed to a method of classifying a scenario, comprising exposing a system to a bioactive condition, representing a response of the system, or portion thereof, to the bioactive condition; and attempting to classify a scenario by database comparison.

Bevilacqua et al. teaches claims 1-2 at the abstract, at col. 2, lines 34-67, and col. 4, lines 1-14. Bevilacqua et al. discusses a method for evaluating the effect on a biological condition affected by an agent and another method for evaluating the effect on a biological condition by a first agent in relation to the effect by a second agent, which the target cells that were administered the agents represent the exposed system as cited in claims 1 and 2 and the agents administered to the target cells represents the bioactive condition to which the system is exposed. Bevilacqua et al. further discusses making calibrated profile data sets that correspond to a measure of the biological condition as affected by the agent, which represents representing a response of the system to the bioactive condition. Bevilacqua et al., at the abstract, discusses a method for evaluating a biological condition of a subject using a calibrated profile data set, which represents classifying the scenario by database comparison. Bevilacqua et al. further discusses the evaluation being a database comparison at col. 4, where evaluating is a comparison of the first instance of the calibrated profile data set in relation to the data in the condition database, which represents classifying a scenario by database comparison.

Bevilacqua et al. teaches claim 7 at col. 4, lines 1-50. Bevilacqua et al. teaches comprising profile data sets, which provide measurements of the biological condition in response to system being exposed to an agent, such as RNA, protein, or numerical gene expression values, which all represent data sufficient to determine a numerical feature space vector. Bevilacqua et al. further teaches using a condition database, where the records are from a population of subjects from known scenarios, for comparing the measured values as a result of the exposure in order to evaluate the resulting biological condition, which represents providing a database for comparison by exposing a system to known scenarios to determine a numerical feature space vector. Bevilacqua et al. also teaches transforming the profile data set to a calibrated profile data set, which represents transforming the data.

Bevilacqua et al. teaches claims 12-16 and 80-82 at col. 18, lines 53-67, col. 19-21, col. 22, lines 1-62, col. 24, lines 16-49, and col. 25, lines 25-30. Bevilacqua et al. teaches at col. 22, lines 57-62, generating signature profiles for different scenarios. At col. 19-21, Bevilacqua et al. teaches extracting the data and creating calibrated profiles and signature panels, which represent calculated locations in feature space representing the characteristic signature of the bioactive condition. Bevilacqua et al. col. 25, teaches using the calibrated profile data sets to determine likelihood that a bioactive condition is a known bioactive condition. Bevilacqua et al. at col. 22, teaches generating signature panels about a previously undescribed agent and may be derived optionally together with a signature profile to use as a gold standard, which is comparing the standard against those panels created later for determining a likelihood

that a complex scenario is a scenario. Bevilacqua et al. at col. 24, lines 16-49, teaches that the invention is automated on a computer program, which inherently reads on calculating relative location of data clusters using software experts.

Bevilacqua et al. teaches claims 108-110, at col. 24, lines 16-49. Bevilacqua et al. discusses the invention being implemented on a computer program and fixed on a tangible medium such as a computer readable medium, for use in a computer system.

Conclusion

No claim is allowed

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jason Sims, whose telephone number is (571)-272-7540.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Andrew Wang can be reached via telephone (571)-272-0811.

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the Central PTO Fax Center. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR § 1.6(d)). The Central PTO Fax Center number is (571)-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

// Jason Sims //

30 October 2006

JOHN S. BRUSCA, PH.D
PRIMARY EXAMINER